

SENATE BILL 1413

By Haynes

AN ACT to amend Tennessee Code Annotated, Title 68, Chapter 11, relative to home medical equipment providers.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 68-11-226, is amended by deleting such section in its entirety.

SECTION 2. Tennessee Code Annotated, Title 68, Chapter 11, is amended by adding Sections 3 through 9 of this act as a new part thereto.

SECTION 3. It is the intent of the general assembly to provide for the licensure of home medical equipment providers and to provide for the development, establishment, and enforcement of basic standards that will ensure quality home medical equipment products and services.

SECTION 4. As used in this act, unless the content otherwise requires:

(1) "Accrediting organizations" means the joint commission on accreditation of healthcare organizations or other national accreditation agencies whose standards for accreditation are comparable to those required by this act for licensure;

(2) "Affiliated person" means any person who directly or indirectly manages, controls, or oversees the operation of a corporation or other business entity that is a

licensee, regardless of whether such person is a partner, shareholder, owner, officer, director, agent, or employee of the entity;

(3) "Applicant" means an individual applicant in the case of a sole proprietorship or any officer, director, agent, managing employee, general manager, or affiliated person or any partner or shareholder having an ownership interest equal to five percent (5%) or greater in the corporation, partnership, or other business entity;

(4) "Board" means the board for licensing healthcare facilities;

(5) "Consumer" or "patient" means any person who uses home medical equipment in such person's place of residence;

(6) "Department" means the department of health;

(7) "General manager" means the individual who has the general administrative charge of the premises of a licensed home medical equipment provider;

(8) "Home medical equipment" includes any product as defined by the Federal Drug Administration's Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under TennCare. "Home medical equipment" includes customized wheelchairs and related seating and positioning but shall not include prosthetics or orthotics or any splints, braces or aids custom fabricated by a licensed healthcare practitioner;

(9) "Home medical equipment provider" means any person or entity that sells or rents or offers to sell or rent to or for a consumer:

(A) Any home medical equipment and services; or

(B) Home medical equipment that requires any home medical equipment services;

(10) "Home medical equipment provider personnel" means persons who are employed by or under contract with a home medical equipment provider;

(11) "Home medical equipment services" means equipment management and consumer instruction, including selection, delivery, setup, and maintenance of equipment and other related services for the use of home medical equipment in the consumer's regular or temporary place of residence;

(12) "Licensee" means the person or entity to whom a license to operate as a home medical equipment provider is issued by the board;

(13) "Moratorium" means a mandated temporary cessation or suspension of the sale, rental or offering of equipment after the imposition of the moratorium. Services related to equipment sold or rented prior to the moratorium must be continued without interruption, unless deemed otherwise by the board;

(14) "Person" means any individual, firm, partnership, corporation or association;

(15) "Premises" means those buildings and equipment which are located at the address of the licensed home medical equipment provider for the provision of home medical equipment services which are in such reasonable proximity as to appear to the public to be a single provider location, and which comply with zoning ordinances;

(16) "Residence" means the consumer's home or place of residence, which may include nursing homes, assisted living facilities, transitional living facilities, adult family-care homes, or other congregate residential facilities.

SECTION 5.

(a) Any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services is subject to licensure under this act.

(b) Any person or entity that holds itself out to the public as providing home medical equipment that typically requires home medical services is subject to licensure under this act.

(c) A home medical equipment provider must be licensed by the board to operate in this state or to provide home medical equipment and services to consumers in this state. A license issued to a home medical equipment provider, unless suspended or revoked, expires two (2) years after its effective date.

(d) A separate license is required of all home medical equipment providers operating on separate premises, even if the providers are operated under the same management.

(e) The following are exempt from home medical equipment provider licensure unless they have a separate company, corporation, or division that is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence pursuant to the provisions of this act:

- (1) Providers operated by the federal government;
- (2) Nursing homes;
- (3) Assisted living facilities when serving their residents;
- (4) Home health agencies;
- (5) Hospices;
- (6) Intermediate care facilities, homes for special services and transitional living facilities;
- (7) Hospitals and ambulatory surgical centers;
- (8) Manufacturers and wholesale distributors when not selling directly to consumers;
- (9) Licensed healthcare practitioners who utilize home medical equipment in the course of their practice, but do not sell or rent home medical equipment to their patients; and
- (10) Pharmacies.

(f) It is unlawful for any person to offer or advertise home medical equipment and services to the public unless such person has a valid license under this act or is exempted from licensure under subsection (e). It is unlawful for any holder of a license issued under this part to advertise or indicate to the public that it holds a home medical equipment provider license other than the one it has been issued.

(g) The following penalties shall be imposed for operating an unlicensed home medical equipment provider:

(1) Any person or entity who operates an unlicensed home medical equipment provider commits a Class E felony.

(2) For any person or entity who has received government reimbursement for services provided by an unlicensed provider, the board shall make a fraud referral to the appropriate government reimbursement program.

(3) For any licensee found to be concurrently operating licensed and unlicensed provider premises the board may impose a civil penalty of not more than five hundred dollars (\$500) per violation, or revoke existing licenses of any or all of the licensee's licensed provider locations until such time as the unlicensed provider premises is licensed.

(h) A provider found to be operating without a license may apply for licensure, but shall cease operations until a license is awarded by the board.

SECTION 6.

(a) Application for an initial license or for renewal of an existing license must be made under oath to the board on forms furnished by it and must be accompanied by the appropriate license fee as required by the board.

(b) The applicant must file with the application satisfactory proof that the home medical equipment provider is in compliance with this act and applicable rules, including:

(1) A report, by category, of the equipment to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of equipment include:

- (A) Respiratory modalities;
- (B) Ambulation aids;
- (C) Mobility aids;
- (D) Sickroom setup; and
- (E) Disposables.

(2) A report, by category, of the services to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of services include:

- (A) Intake;
- (B) Equipment selection;
- (C) Delivery;
- (D) Setup and installation;
- (E) Patient training;
- (F) Ongoing service and maintenance; and
- (G) Retrieval.

(3) A listing of those with whom the applicant contracts, both the providers the applicant uses to provide equipment or services to its consumers and the providers for whom the applicant provides services or equipment.

(c) The applicant for initial licensure must demonstrate financial ability to operate, which may be accomplished by the submission of a fifty thousand dollar (\$50,000) surety bond to the board.

(d) An applicant for renewal who has demonstrated financial inability to operate must demonstrate financial ability to operate before such applicant's license will be renewed.

(e) Each applicant for licensure must comply with the following requirements:

(1) Upon receipt of a completed, signed, and dated application, the board shall initiate a criminal background check of the applicant. As used in this subsection, the term "applicant" means the general manager and the financial officer or similarly titled individual who is responsible for the financial operation of the licensed facility. The applicant shall supply fingerprint samples, or submit to a criminal history records check to be conducted by the Tennessee bureau of investigation.

(2) The board may require a criminal background check for a member of the board of directors of the licensee, or an officer or an individual owning five percent (5%) or more of the licensee if the board has probable cause to believe that such individual has been convicted of a felony.

(3) Any costs incurred by the Tennessee bureau of investigation in conducting such investigation of applicants shall be paid by the licensee. Payment of such costs are to be made in accordance with the provisions of § 38-6-103.

(4) Each applicant must submit to the board, with its application, a description and explanation of any exclusions, permanent suspensions or terminations of the applicant from the Medicare or Medicaid programs. Proof of compliance with disclosure of ownership and control interest requirements of the Medicaid or Medicare programs shall be accepted in lieu of this submission.

(5) Each applicant must submit to the board a description and explanation of any felony by a member of the board of directors of the applicant, its officers,

or any individual owning five percent (5%) or more of the applicant. This requirement does not apply to a director of a not-for-profit corporation or organization if the director serves solely in a voluntary capacity for the corporation or organization, does not regularly take part in the day-to-day operational decisions of the corporation or organization, receives no remuneration for such director's services on the corporation's or organization's board of directors, and has no financial interest and has no family members with a financial interest in the corporation or organization, provided that the director and the not-for-profit corporation or organization include in the application a statement affirming that the director's relationship to the corporation satisfies the requirements of this provision.

(6) A license may not be granted to any potential licensee if any applicant, administrator, or financial officer has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to, any felony.

(7) The board may deny or revoke licensure to any potential licensee if any applicant:

(A) Has falsely represented a material fact in the application or has omitted any material fact from the application; or

(B) Has had prior Medicaid or Medicare action taken against the applicant as set forth in subdivision (3).

(8) Upon licensure renewal each applicant must submit to the board, under penalty of perjury, an affidavit of compliance with the background screening provisions of this section.

(f) The home medical equipment provider must also obtain and maintain professional and commercial liability insurance. Proof of liability insurance shall be submitted with the application. The board shall set the required amounts of liability

insurance by rule, but the required amount shall not be less than two hundred-fifty thousand dollars (\$250,000) per claim. In the case of contracted services, the contractor shall have liability insurance of not less than two hundred-fifty thousand dollars (\$250,000) per claim.

(g) A provisional license shall be issued to an approved applicant for initial licensure for a period of ninety (90) days, during which time a survey must be conducted demonstrating substantial compliance with this section. A provisional license shall also be issued pending the results of an applicant's Tennessee bureau of investigation report of background screening confirming that all standards have been met. If substantial compliance is demonstrated a license shall be issued to expire two (2) years after the effective date of the provisional license.

(h) Ninety (90) days before the expiration date, an application for license renewal must be submitted to the board under oath on forms furnished by the board, and a license shall be renewed if the applicant has met the requirements established under this act and applicable rules. The home medical equipment provider must file with the application satisfactory proof that it is in compliance with this part and applicable rules. The home medical equipment provider must submit satisfactory proof of its financial ability to comply with the requirements of this part.

(i) When a change of ownership of a home medical equipment provider occurs the prospective owner must submit an initial application for a license at least fifteen (15) days before the effective date of the change of ownership. An application for change of ownership of a license is required when ownership, a majority of the ownership, or controlling interest of a licensed home medical equipment provider is transferred or assigned and when a licensee agrees to undertake or provide services to the extent that legal liability for operation of the home medical equipment provider rests with the licensee. A provisional license shall be issued to the new owner for a period of ninety

(90) days during which time all required documentation must be submitted and a survey must be conducted demonstrating substantial compliance with this section. If substantial compliance is demonstrated a license shall be issued to expire two (2) years after the issuance of the provisional license.

(j) When a change of the general manager of a home medical equipment provider occurs the licensee must notify the board of the change within forty-five (45) days and must provide evidence of compliance with the background screening requirements in subsection (e); except that a general manager who has met the standards for the abuse registry background check and the criminal background check, but for whom background screening results from the Tennessee bureau of investigation have not yet been received, may be employed pending receipt of the Tennessee bureau of investigation background screening report.

(k) All licensure fees required of a home medical equipment provider are nonrefundable. The board shall set the fees in an amount that is sufficient to cover its costs in carrying out its responsibilities under this act. Provided, state, county, or municipal governments applying for licenses under this act are exempt from the payment of license fees.

(l) An applicant for initial licensure renewal, or change of ownership, shall pay a license processing fee not to exceed three hundred dollars (\$300) to be paid by all applicants and an inspection fee not to exceed four hundred dollars (\$400) to be paid by all applicants except those not subject to licensure inspection by the board.

(m) When a change is reported which requires issuance of a license, a fee shall be assessed. The fee must be based on the actual cost of processing and issuing the license.

(n) When a duplicate license is issued a fee must be assessed not to exceed the actual cost of duplicating and mailing such duplicate license.

(o) When applications are mailed out upon request, a fee must be assessed, not to exceed the cost of the printing, preparation, and mailing.

(p) The license must be displayed in a conspicuous place in the administrative office of the home medical equipment provider and is valid only while in the possession of the person or entity to which it is issued. The license may not be sold, assigned, or otherwise transferred, voluntarily or involuntarily, and is valid only for the home medical equipment provider and location for which originally issued.

(q) A home medical equipment provider, against whom a proceeding for revocation or suspension or for denial of a renewal application is pending at the time of license renewal, may be issued a provisional license effective until final disposition by the board of such proceedings. If judicial relief is sought from the final disposition, the court that has jurisdiction may issue a temporary permit for the duration of the judicial proceeding.

SECTION 7.

(a) The board may deny, revoke or suspend a license, or impose a civil penalty not to exceed five thousand dollars (\$5,000) per violation, per day.

(b) Any of the following actions by a home medical equipment provider or any of its employees is grounds for administrative action or civil penalties by the board:

(1) Violation of this act or of applicable rules; or

(2) An intentional, reckless, or negligent act that materially affects the health or safety of a patient.

(c) The board may deny or revoke the license of any applicant that:

(1) Made a false representation or omission of any material fact in making the application, including the submission of an application that conceals the controlling or ownership interest, or any officer, director, agent, managing

employee, affiliated person partner, or shareholder who may not be eligible to participate;

(2) Has been previously found by any professional licensing, certifying, or standards board or agency to have violated the standards or conditions relating to licensure or certification or the quality of services provided. "Professional licensing, certifying or standards board or agency" shall include, but is not limited to, practitioners, healthcare facilities, programs, or services, or residential care, treatment programs, or other human services; or

(3) Has been or is currently excluded, suspended, or terminated from, or has involuntarily withdrawn from, participation in TennCare or any other state's Medicaid program, or participation in the Medicare program or any other governmental or private health care or health insurance program.

(d) The board may issue an emergency order immediately suspending or revoking a license when it determines that any condition within the responsibility of the home medical equipment provider presents a clear and present danger to public health and safety.

(e) The board may impose an immediate moratorium on any licensed home medical equipment provider when the board determines that any condition within the responsibility of the home medical equipment provider presents a threat to public health or safety.

SECTION 8.

(a) The department shall make or cause to be made such inspections and investigations, as it considers necessary, including:

(1) Licensure inspections;

(2) Inspections directed by the federal healthcare financing administration;

(3) Licensure complaint investigations, including full licensure investigations with a review of all licensure standards as outlined in the administrative rules. Complaints received by the board from individuals, organizations, or other sources are subject to review and investigation by the board.

(b) The department shall accept in lieu of its own periodic inspections for licensure, submission of a survey or inspection of an accrediting organization, provided the accreditation of the licensed home medical equipment provider is not provisional and provided the licensed home medical equipment provider authorizes release of, and the board receives the report of, the accrediting organization.

SECTION 9. Home medical equipment providers shall:

(1) Offer and provide home medical equipment and services, as necessary, to consumers who purchase or rent equipment that requires such services.

(2) Provide at least one (1) category of equipment directly, filling orders from its own inventory.

(3) Respond to orders received for other equipment by filling those orders from its own inventory or inventory from other companies with which it has contracted to fill such orders; or customizing or fitting items for sale from supplies purchased under contract.

(4) Maintain trained personnel to coordinate order fulfillment and schedule timely equipment and service delivery.

(5) As necessary in relation to the sophistication of the equipment and services being provided, ensure that delivery personnel are appropriately trained to conduct an environment and equipment compatibility assessment; appropriately and safely set up the equipment; instruct patients and caregivers in the safe operation and client

maintenance of the equipment; and recognize when additional education or follow-up patient compliance monitoring is appropriate.

SECTION 10. Tennessee Code Annotated, Section 68-11-201, is amended by deleting items (17) and (18) in their entirety.

SECTION 11. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 12. For the purpose of promulgating rules and regulations, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2002, the public welfare requiring it.